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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,453	09/30/2003	Thomas Ryan	GYN-5009	4128
27777	7590	04/19/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PRONE, CHRISTOPHER D	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/674,453	Applicant(s) RYAN ET AL.	
	Examiner Christopher D Prone	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/30/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to an electrosurgical instrument for transecting an organ, classified in class 606, subclass 48.
- II. Claim 19-21, drawn to a method for electro-surgically transecting an organ, classified in class 606, subclass 114.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process including use for gripping and severing a vein.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: an electrosurgical instrument for transecting an organ.

Species 1 shown in figure 1a

Species 2 shown in figure 2a

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are considered generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and **a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Melissa Szanto on 4/8/05 a provisional election was made without traverse to prosecute the invention 1 and species 2, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office

action. Claims 19-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "118" has been used to designate both an electrical wire one page 8 in line 11 and a deployment device one page 8 in line 26 of the current specification.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "120" has been used to designate both an electrical wire one page 8 in line 11 and a protrusion one page 9 in line 18.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the

changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 125. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Claim 4 has been skipped. Therefore misnumbered claims 5-21 have been renumbered 4-20.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5,976,129 Desai.

In reference to claim 1, Desai discloses the same invention being an electrosurgical instrument for transecting an organ, comprising: an introducer referenced as element 434, a conductive wire referenced as element 432 movable between an undeployed position wherein the conductive wire is substantially positioned within the channel and a deployed position wherein a portion of the conductive wire is deployed from and positioned outside of the introducer described in column 4 on line 56

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through line 16 of column 5, wherein in the deployed position said portion of the conductive wire has a substantially looped configuration shown in figures 6, 32, and 36 of Desai; a deployment device movably coupled to the introducer and movable between a first position and a second position referenced as element 436, the deployment device being engaged with the conductive wire such that movement of the deployment device between the first and second positions causes the conductive wire to move between the undeployed and deployed positions; a capture element referenced as element 550 at a distal end of the introducer for securing the distal end of the conductive wire to the introducer when the conductive wire is in the deployed position, wherein, when the conductive wire is in the deployed position and when the distal end of the conductive wire is secured to the introducer by the capture element, the deployment device is movable toward the first position to thereby cinch the conductive wire substantially without moving the introducer shown in figures 1-61 of Desai.

In reference to claim 2, Desai discloses the same invention wherein the electrosurgical instrument is a bipolar instrument and the introducer further includes a conductive portion, and wherein the conductive wire is an active electrode and the conductive portion of the introducer is a return electrode described in column 24 on lines 1-29 of Desai.

In reference to claim 3, Desai discloses the same invention comprising a bipolar generator having a first pole electrically coupled to the active electrode and a second pole electrically coupled to the return electrode described in column 4 on lines 46-56 of Desai.

In reference to claims 5 and 6, Desai discloses the same invention wherein the conductive wire is made from the shape memory alloy nitinol described in column 5 on lines 6-10 of Desai.

In reference to claim 13, Desai discloses the same invention wherein the introducer further comprises shaft extension portion having a first diameter and a handle portion adjacent the shaft extension portion having a second diameter greater than the first diameter, and wherein the channel extends through the shaft extension portion and into the handle portion shown in figure 33 of Desai.

In reference to claim 14, Desai discloses the same invention wherein the conductive wire further comprises a protrusion at the distal end shown in figure 35 and referenced as element 535 in Desai.

In reference to claim 15, Desai discloses the same invention being a bipolar electrosurgical instrument for transecting an organ, comprising: an introducer referenced as element 434 having a conductive portion forming a return electrode; a conductive wire referenced as element 432 comprised of a shape memory alloy described in column 5 on lines 6-10 of Desai; slidably receivable within the channel and movable between an undeployed position wherein the conductive wire is substantially positioned within the channel and a deployed position wherein a portion of the conductive wire is deployed from and positioned outside of the introducer, wherein in the deployed position said portion of the conductive wire has a substantially looped configuration shown in figures 6, 32, and 36 of Desai, the conductive wire forming an active electrode; a deployment device referenced as element 436 movably coupled to

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the introducer and movable between a first position and a second position, the deployment device being engaged with the conductive wire such that movement of the deployment device between the first to second positions causes the conductive wire to move between the undeployed and deployed positions respectively; a capture element referenced as element 550 at a distal end of the introducer for securing the distal end of the conductive wire to the introducer when the conductive wire is in the deployed position, wherein, when the conductive wire is in the deployed position and when the distal end of the conductive wire is secured to the introducer by the capture element, the deployment device is movable toward the first position to thereby cinch the conductive wire substantially without moving the introducer.

In reference to claim 16, Desai discloses the same invention comprising a bipolar generator having a first pole electrically coupled to the active electrode and as second pole electrically coupled to the return electrode described in column 4 on lines 46-56 of Desai.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103 as being unpatentable over United States Patent 5,976,129 Desai in view of United States Patent 4,493,320 Treat.

Desai discloses the invention substantially as claimed being an electrosurgical instrument for transecting an organ. However, Desai does not disclose that the conductive wire is comprised of spring steel.

Treat teaches the use of a bipolar electro-cautery surgical snare with wires comprised of spring steel in the same field of endeavor for the purpose of providing an easily shapeable conductive wire.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the spring steel wire of Treat with electrosurgical instrument of Desai in order to a conductive wire that is cheap and easily moldable.

Claims 8-12, 17, and 18 are rejected under 35 U.S.C. 103 as being unpatentable over United States Patent 5,976,129 Desai in view of United States Patent 5,782,839 Hart.

Desai discloses the invention substantially as claimed being an electrosurgical instrument for transecting an organ comprising a capture element referenced as element 550, that pivots about a pivot point at a distal end of the introducer for securing the distal end of the conductive wire to the introducer when the conductive wire is in the deployed position, wherein, when the conductive wire is in the deployed position and when the distal end of the conductive wire is secured to the introducer by the capture element, the deployment device is movable toward the first position to thereby cinch the

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conductive wire substantially without moving the introducer. However, Desai does not disclose an actuator for engaging the capture element.

Hart teaches the use of an actuator referenced as element 78 and an introducer with a recess shown in figures 2-4 in the same field of endeavor for the purpose of engaging the wire loop and providing a secure connection.

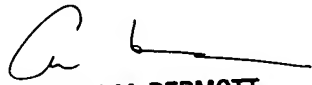
It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the capture element actuator and introducer recess of Hart with the electrosurgical instrument of Desai in order to provide a movable capture element which will secure the looping element to the introducer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


CDP


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700